This rejection is respectfully traversed. The claims themselves are directed to the use of purified polynucleotides which may be used as genetic markers. Whether these polynucleotides translate into proteins or not does not necessarily diminish their utility as gene markers. The specification states "Polynucleotides in the form of DNA, cDNA, genomic DNA, nucleic acid analogs and synthetic DNA are within the scope of the invention." (p. 21, lines 35-36).

The Examiner states that the specification essentially gives an invitation to experiment to elaborate a functional use for the disclosed nucleic acids. Applicant vigorously disagrees.

The Examiner states that there are no examples or teaching in the specification that would indicate that normal gastrointestinal (GI) tract tissue does not express the polynucleotides of SEQ ID NOS: 1, 2, 23, 24, 25. These claims have been cancelled.

Applicant seeks to clarify that normal GI tract tissue does express the polynucleotides of SEQ ID NOS:1, 2, 23, 24, 25 since normal GI tract tissue is the host tissue of these polynucleotides. The polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existent. Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case GI tract tissue) into other areas of the body. Thus, these polynucleotides are useful as markers for the detection of disease in GI tract tissue.

The Examiner states that the specification does not demonstrate that the detection of these polynucleotide sequences is indicative of the presence of gastrointestinal disease or any other disease. Applicant previously described diagnostic techniques used with prostate specific antigen (PSA) and carcinoembryonic antigen (CEA). Further, Applicant has cited several references in the specification (for example, at p. 3, lines 5-7), which show that a detection technique based on overexpression of a specific polynucleotide outside its host tissue is one that is well known in the art. Therefore undue experimentation would not be necessary to use well-known techniques for the detection

of disease with the polynucleotides of the instant invention in order to detect GI tract disease.

Applicant asserts that the examples and methods disclosed in the specification are enabling for, at the least GI tract diseases that may be detected using gene markers and related gene marker technology as are well known in the cancer diagnostic art. Applicant respectfully submits that the new claims are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-3 are also rejected under 35 USC 112, first paragraph as containing subject matter that, because it is not supported by either an asserted utility or a well-established utility, was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. These claims have been cancelled. In view of the above remarks, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,
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